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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION

ASTRAZENECA PHARMACEUTICALS LP and ASTRAZENECA UK LIMITED,

Plaintiffs,

v.

HANDA PHARMACEUTICALS, LLC, and JOHN DOE ENTITY,

Defendants.

No. C08-04026 EMC

NOTICE OF PENDENCY OF OTHER ACTION OR PROCEEDING

(Civil L.R. 3-13)

The present action is one for patent infringement under the Hatch-Waxman Act. Pursuant to Civil L.R. 3-13, plaintiffs AstraZeneca Pharmaceuticals LP and AstraZeneca UK Limited (collectively, "AstraZeneca") hereby notify the Court of an essentially identical action earlier filed in the United States District Court for the District of New Jersey and pending there before the Honorable Joel A. Pisano. That action is *AstraZeneca Pharmaceuticals LP, et al. v. Handa Pharmaceuticals, LLC, et al.*, Civil Action No. 08-cv-3773 (JAP)(TJB) ("the New Jersey Handa action"). The parties in the two actions are the same. AstraZeneca expects that it will seek an order staying the present action pending the resolution of an expected jurisdictional challenge by defendant Handa Pharmaceuticals, LLC ("Handa") in the New Jersey Handa action, or, in the alternative, an order transferring the present action to New Jersey.

Background

Pursuant to the Hatch-Waxman Act, a branded pharmaceutical company is required to identify to the U.S. Food and Drug Administration ("FDA") the number of any patent that covers an approved drug or its use. 21 U.S.C. § 355(b)(1). The FDA lists such patents in its so-called "Orange Book." AstraZeneca is the owner of two Orange Book-listed patents that cover its approved quetiapine fumarate extended release tablets, sold under the name Seroquel XR®. Those two patents are U.S. Patent No. 4,879,288, covering the quetiapine fumarate active ingredient ("the '288 patent") and U.S. Patent No. 5,948,437, covering a sustained release formulation of quetiapine fumarate ("the '437 patent").

A generic drug company may file with the FDA an Abbreviated New Drug Application ("ANDA") seeking approval to sell commercially a generic version of an approved drug. If a patent is listed in the Orange Book for the approved drug, the ANDA-filer must certify to the FDA either that it will wait for patent expiration to market the generic drug, or that, in its opinion, the patent will not be infringed by the proposed generic drug or is invalid. 21 U.S.C. § 355(j)(2)(A)(vii)(III) and (IV). The latter type of certification is known as a "Paragraph IV" certification. The filing of an ANDA with a Paragraph IV certification is an act of patent infringement. 35 U.S.C. § 271(e)(2)(A). Defendant Handa filed an ANDA with a Paragraph IV certification with respect to both the '288 and the '437 patents.

An ANDA filer making a Paragraph IV certification is required to notify the patent owner of the ANDA filing. In a letter dated July 10, 2008, Handa notified AstraZeneca that Handa had filed its ANDA for generic quetiapine fumarate extended release tablets. If a patent owner brings suit for patent infringement against the ANDA filer within 45 days after the patent owner's receipt of such notice, FDA approval of the ANDA is automatically stayed for a period of 30 months. 21 U.S.C. § 355(j)(5)(B)(iii). On July 28, 2008, AstraZeneca filed its complaint in the New Jersey Handa action, within the 45-day period.

AstraZeneca properly filed that action in New Jersey. First, as Handa has announced on its website, Handa does not itself intend to make or distribute the proposed ANDA products. Instead, it intends to establish a partnership with "organizations that are experts in manufacturing and distribution to complete these functions." AstraZeneca believes that Handa's partners—and through them, Handa—have the requisite contacts with New Jersey.

Second, already pending before the same district judge in New Jersey was another Hatch-Waxman suit involving the same '288 patent. In 2005 and 2006, AstraZeneca filed patent infringement actions involving the '288 patent against Teva Pharmaceuticals USA Inc. and Teva Pharmaceutical Industries Ltd.[1] And, in 2007, AstraZeneca filed another patent infringement action against Sandoz, Inc., also involving the '288 patent.[2] The Teva and Sandoz actions were consolidated, and on July 1, 2008, Judge Pisano granted AstraZeneca's motion for summary judgment that the '288 patent is not unenforceable for inequitable conduct. Judge Pisano entered a final judgment on July 9, 2008, in the Teva and Sandoz actions, and those defendants have now appealed that judgment to the United States Court of Appeals for the Federal Circuit.

Handa's Expected Jurisdictional Challenge in New Jersey Forced AstraZeneca to File the Present "Protective" Suit

Based on pre-suit correspondence between counsel, AstraZeneca expects that Handa will challenge the New Jersey court's personal jurisdiction over it. To guard against the possibility that,

[1] The actions against the Teva defendants are *AstraZeneca Pharmaceuticals LP v. Teva Pharmaceuticals USA, Inc.*, Civil Action Nos. 05-cv-5333 (JAP)(TJB), 06-cv-1528 (JAP)(TJB), 07-cv-3001 (JAP)(TJB).

[2] The action against Sandoz is *AstraZeneca Pharmaceuticals LP v. Sandoz Inc.*, Civil Action No. 07-cv-1632 (JAP)(TJB).

if the New Jersey court were to dismiss the New Jersey Handa action for lack of personal jurisdiction, Handa would then assert that no automatic 30-month stay should apply because no pending suit was brought within the statutory 45-day period, AstraZeneca was forced to file the present action as a "protective" suit. Several decisions have recognized that such patent suits are prudent on the part of a patent owner in a Hatch-Waxman case. (See, e.g., *PDL Biopharma, Inc. v. Sun Pharm. Indus., Ltd.*, No. 07-11709, 2007 WL 2261386, at *2 (E.D. Mich., Aug. 6, 2007); *Abbott Laboratories v. Mylan Pharmaceuticals, Inc.*, No. 05 C 6561, 2006 WL 850916, *8 (N.D. Ill., Mar. 28, 2006).)

This Dispute Should Be Adjudicated in New Jersey

AstraZeneca respectfully submits that this dispute with Handa should proceed in New Jersey, rather than California.

First, New Jersey is AstraZeneca's choice of forum, a choice that generally is accorded "substantial deference." *Piper Aircraft Co. v. Reyno*, 454 U.S. 235, 255 (1981).

Second, New Jersey is considerably more convenient than California to AstraZeneca's witnesses and the production of AstraZeneca's documents. As is typical of Hatch-Waxman litigation, AstraZeneca's discovery burdens in this dispute (which will encompass the Patent and Trademark Office prosecution histories for its '288 and '437 patents, the research and development records leading to the creation of the patented product, and the NDA for the patented product) are likely to be far greater than Handa's.

Third, the present action is duplicative of the New Jersey Handa action, and serves no purpose other than to ensure that AstraZeneca does not lose its 30-month stay if Handa's expected jurisdictional challenge in New Jersey is successful.

Fourth, AstraZeneca believes in good faith that Handa in fact is subject to personal jurisdiction in New Jersey, and that future discovery will substantiate this belief.

Finally, the judge to which the New Jersey Handa action has been assigned already possesses extensive experience with the subject matter in suit.

For at least these reasons, AstraZeneca intends to move to stay this action or to transfer it to the District of New Jersey. The stay and/or transfer of this action will avoid conflicts, conserve resources, and otherwise promote the efficient determination of the matter.

Respectfully submitted,

FILICE BROWN EASSA & MCLEOD LLP

Dated: September 3, 2008

By: /s/ Paul R. Johnson

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